

CLAIMS

We claim:

1. An immunogen which comprises

5 a) at least one first antigenic determinant that includes at least one B-cell epitope and/or at least one CTL epitope, and

10 b) at least one second antigenic determinant that includes a T helper cell epitope (T_H epitope),

15 wherein each of the at least one first and second antigenic determinants are coupled to a pharmaceutically acceptable activated polyhydroxypolymer carrier.

2. The immunogen according to claim 1, wherein the at least one first antigenic determinant is constituted by an amino acid sequence and/or wherein the at least one second antigenic 15 determinant is constituted by an amino acid sequence.

3. The immunogen according to claim 1, wherein the at least first and at least second antigenic determinants are coupled to the polyhydroxypolymer carrier via a bond cleavable by a peptidase.

4. The immunogen according to claim 1, wherein the at least first 20 and at least second antigenic determinants are coupled to the activated polyhydroxypolymer carrier via an amide bond or a peptide bond.

5. The immunogen according to claim 4, wherein the at least first and at least second antigenic determinants each provide for the nitrogen moiety of their respective bond.
6. The immunogen according to claim 1, wherein the
5 polyhydroxypolymer carrier is substantially free of amino acid residues.
7. The immunogen according to claim 5, wherein the at least first and at least second antigenic determinants are bound to the activated polyhydroxypolymer via a nitrogen atom at the N-
10 terminus of an amino acid sequence.
8. The immunogen according to claim 1 wherein the polyhydroxypolymer is water soluble.
9. The immunogen according to claim 1 wherein the polyhydroxypolymer is water insoluble.
- 15 10. The immunogen according to claim 1, wherein the polyhydroxypolymer is selected from naturally occurring polyhydroxy compounds and synthetic polyhydroxy compounds.
11. The immunogen according to claim 1, wherein the polyhydroxypolymer is a polysaccharide selected from acetan,
20 amylopectin, gum agar-agar, agarose, alginates, gum Arabic, carregeenan, cellulose, cyclodextrins, dextran, furcellaran, galactomannan, gelatin, ghatti, glucan, glycogen, guar, karaya, konjac/A, locust bean gum, mannan, pectin, psyllium, pullulan, starch, tamarine, tragacanth, xanthan, xylan, and xyloglucan.

12. The immunogen according to claim 11, wherein the polyhydroxypolymer is dextran.

13. The immunogen according to claim 1, wherein the polyhydroxypolymer is selected from highly branched
5 poly(ethyleneimine) (PEI), tetrathienylene vinylene, Kevlar (long chains of poly-paraphenyl terephthalamide), Poly(urethanes), Poly(siloxanes), polydimethylsiloxane, silicone, Poly(methyl methacrylate) (PMMA), Poly(vinyl alcohol), Poly(vinyl pyrrolidone), Poly(2-hydroxy ethyl methacrylate), Poly(N-vinyl pyrrolidone), Poly(vinyl alcohol), Poly(acrylic acid),
10 Polytetrafluoroethylene (PTFE), Polyacrylamide, Poly(ethylene-co-vinyl acetate), Poly(ethylene glycol) and derivatives, Poly(methacrylic acid), Polylactides (PLA), Polyglycolides (PGA), Poly(lactide-co-glycolides) (PLGA), Polyanhydrides, and
15 Polyorthoesters.

14. The immunogen according to claim 1, wherein the average molecular weight of the polyhydroxypolymer before activation is at least 500.

15. The immunogen according to claim 1, wherein the
20 polyhydroxypolymer is activated with functional groups selected from tresyl (trifluoroethylsulphonyl), maleimido, p-nitrophenyl cloroformate, and tosyl (p-toluenesulfonyl).

16. The immunogen according to claim 1 that further comprises
that at least one moiety is coupled to the polyhydroxypolymer,
25 said at least one moiety being selected from the group consisting of an immune stimulating moiety or a targeting moiety.

17. The immunogen according to claim 16, wherein the at least one moiety is a peptide.
18. The immunogen according to claim 1 which is capable of being taken up by an antigen presenting cell (APC).
- 5 19. The immunogen according to claim 18, which is capable of being processed by the APC whereby the APC presents the T_H epitope on its surface bound to an MHC Class II molecule.
20. The immunogen according to preceding claim 1 wherein the at least one first and second antigenic determinants are not derived
10 from the same naturally occurring molecule.
21. The immunogen according to claim 20, wherein the at least one and the at least second antigenic determinants do not occur naturally in the same species.
22. The immunogen according to claim 1, wherein the T_H epitope
15 binds strongly to at least one human MHC Class II molecule.
23. The immunogen according to claim 22, wherein the T_H epitope is a promiscuous T_H epitope in humans.
24. An immunogenic composition for raising an immune response against an antigen in a mammal, including a human being,
20 comprising the immunogen according to claim 1 in admixture with a pharmacologically and immunologically acceptable carrier, excipient or diluent, and optionally with an adjuvant.
25. The immunogenic composition according to claim 24, wherein the adjuvant is selected from the group consisting of an immune

targeting adjuvant; an immune modulating adjuvant such as a toxin, a cytokine and a mycobacterial derivative; an oil formulation; a polymer; a micelle forming adjuvant; a saponin; an immunostimulating complex matrix (an ISCOM matrix); a particle; 5 DDA; aluminium adjuvants; DNA adjuvants; γ -inulin; and an encapsulating adjuvant.

26. A method for immunizing an animal, including a human being, against an antigen of choice, the method comprising administering an effective amount of the immunogen according to claim 1 to the 10 animal, wherein the antigen shares the at least one first antigenic determinant with the immunogen.

27. A method for immunizing an animal, including a human being, against an antigen of choice, the method comprising administering an effective amount of the immunogenic composition according to 15 claim 24 to the animal, wherein the antigen shares the at least one first antigenic determinant with the immunogen.

28. A method for immunizing an animal, including a human being, against an antigen of choice, the method comprising administering an effective amount of the immunogenic composition according to 20 claim 25 to the animal, wherein the antigen shares the at least one first antigenic determinant with the immunogen.

29. The method according to claim 26, wherein the immunogen is administered via a route selected from a route selected from the group consisting of the parenteral route such as the 25 intracutaneous, the subcutaneous, and the intramuscular routes; the peritoneal route; the oral route; the buccal route; the

sublingual route; the epidural route; the spinal route; the anal route; and the intracranial route.

30. The method according to claim 27, wherein the immunogenic composition is administered via a route selected from a route selected from the group consisting of the parenteral route such as the intracutaneous, the subcutaneous, and the intramuscular routes; the peritoneal route; the oral route; the buccal route; the sublingual route; the epidural route; the spinal route; the anal route; and the intracranial route.

10 31. The method according to claim 28, wherein the immunogen or the immunogenic composition is administered via a route selected from a route selected from the group consisting of the parenteral route such as the intracutaneous, the subcutaneous, and the intramuscular routes; the peritoneal route; the oral route; the buccal route; the sublingual route; the epidural route; the spinal route; the anal route; and the intracranial route.

32. The method according to claim 26, wherein the effective amount of the immunogen is between 0.5 μ g and 2,000 μ g.

33. The method according to claim 26, which includes at least one administration per year, such as at least 2, at least 3, at least 4, at least 6, and at least 12 administrations per year.

34. The method according to claim 27, which includes at least one administration per year, such as at least 2, at least 3, at least 4, at least 6, and at least 12 administrations per year.

35. The method according to claim 28, which includes at least one administration per year, such as at least 2, at least 3, at least 4, at least 6, and at least 12 administrations per year.

36. The method according to claim 26, wherein the immunogen or
5 the immunogenic composition is contained in a virtual lymph node
(VLN) device.

37. The method according to claim 27, wherein the immunogen or
the immunogenic composition is contained in a virtual lymph node
(VLN) device.

10 38. The method according to claim 28, wherein the immunogen or
the immunogenic composition is contained in a virtual lymph node
(VLN) device.